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The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2003D-0263; Draft Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency (Draft Guidance).

Dear Sir or Madam:

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President and
Chief Executive Officer

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The National Food Processors Association (NFPA) takes this opportunity to comment on the Draft Guidance made available on July 23. NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, food security and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international Members. NFPA Members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

General Comments

NFPA appreciates the Food and Drug Administration's (FDA) effort to establish a general policy for implementing Section 408(l)(5) (channels of trade provision) of the Federal Food, Drug, and Cosmetic Act (FFDCA). An understanding of Agency policy and intent will facilitate advance planning and eventual compliance by affected parties. However, it remains essential, as indicated in the Draft Guidance, for FDA to continue the current approach of issuing guidance on a case-by-case basis for each pesticide that is subject to EPA tolerance revocation, suspension, or modification. Each pesticide tolerance action by EPA will potentially have unique features involving not only the characteristics of the pesticide, but also the conditions of registration and subsequent tolerance action. For example, in a recent proposal (68 FR 54451) to accept voluntary cancellation of the registration for the pesticide molinate, which is registered for use on rice, EPA is proposing to allow continued sale at a decreasing percentage of a 2002 baseline into 2008. On June 30, 2008 the registrants will be prohibited from selling or distributing molinate. However, use of existing stocks is proposed until

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August 31, 2009 to permit use during the 2009 growing season. No indication is given as to when action on the tolerance for molinate on rice will be taken.

NFPA offers the example of the proposed cancellation of the registration for molinate to highlight two points. First, the EPA proposal to cancel is based on requests for voluntary cancellation by the registrants of the pesticide. This situation happens much more frequently than direct action due to the finding of an unacceptable dietary risk. NFPA believes that FDA must be prepared to respond with guidance in these and similar situations. Second, the actual date after which molinate cannot be used is almost twelve months after the date on which registrants propose to stop sale and distribution of the product. In any FDA guidance for the channels of trade provision concerning molinate, for example, NFPA would expect a clear indication that the key date regarding the cancellation of the product is the date after which use is prohibited not the date after which sale and distribution is prohibited. NFPA urges FDA to closely coordinate and communicate with EPA on any actions to make sure allowances for use of existing pesticide stocks are reflected in FDA's guidance.

NFPA agrees with FDA's approach in the Draft Guidance on the following points:

- Allowing flexibility in the documentation upon which a showing of legal application can be based. NFPA notes that in some instances, the responsible party may be able to document more precisely the date on which the pesticide was applied.

- FDA's proposed approach for enforcement with respect to multiple ingredient foods.

- FDA's use of the methods of pesticide analysis cited in FDA's compliance programs for pesticide residues in domestic and imported foods in the proposed enforcement approach with respect to FDA "finding" a food containing a relevant pesticide residue.

<u>FDA's determination that during a given period legal use will be presumed is appropriate, but may be limited by data availability.</u>

NFPA supports FDA's intent to establish periods of time during which the finding of a pesticide residue at or below the acceptable tolerance will be presumed to be the result of a legal application. As noted above, NFPA urges FDA to be certain the last date established for determining when legal application could occur reflects the conditions of EPA's action to cancel a registration. Also, NFPA believes information for determining when a particular commodity (fresh, frozen, or otherwise processed) will remain in the channels of trade and for estimating pesticide degradation (or lack of degradation) in foods may be very limited in the absence of additional information from the public. NFPA's concern is that generalized expectations regarding the length of time fresh

commodities or processed foods remain in commerce could underestimate the time legal application of a pesticide can be presumed. The specific fresh or processed commodity involved may be significant. For example, some commodities, such as apples, may be kept in refrigerated conditions for up to one full year after harvesting and subsequently used in the fresh market or in further processed products. Processed apple products, in turn, may be in the channels of trade for four or five years.

EPA may have limited or no applicable information on the degradation/or lack of degradation of pesticides in relevant commodities. EPA does not require extensive data from registrants regarding residue degradation in either fresh or processed foods and may have information representative of crop groupings rather than specific commodities. NFPA assumes FDA will not commission new studies, but intends to rely primarily on EPA information and data. NFPA's concern is that relying on available data will limit FDA's ability to accurately determine the time periods under which legal application of a pesticide can be presumed.

NFPA urges FDA to provide the opportunity for public comment on proposed guidance prior to adoption as FDA's guidance for enforcement. The Draft Guidance describes the intent of FDA is to place a Level 2 guidance on the Agency's website in conjunction with EPA's proposed action concerning the particular pesticide chemical. NFPA urges FDA to make sure the availability of the Level 2 guidance is clearly indicated on the website and, preferably, through a Federal Register notice. FDA is also urged to seek reference to the guidance in the EPA proposed action. FDA's Good Guidance Practices (21 CFR 10.115) suggests Level 2 guidance may become immediately implemented once it is posted on the FDA website, unless FDA indicates otherwise when the document is made available. NFPA strongly urges FDA to use the Agency's discretion and actively solicit public comment before a pesticide specific guidance is implemented. This may be particularly significant if EPA has limited information about the relevant pesticide or the EPA action is substantially changed from what is originally proposed.

FDA should increase the estimated number of Level 2 guidance actions that may be needed.

In the notice for the Draft Guidance (68 FR 43535), FDA states that the Agency assumes two pesticide tolerances are altered per year. NFPA believes this is a major under estimate. NFPA believes the channels of trade provision (FFDCA Section 408(l)(5)) applies to any EPA action that revokes, suspends, or modifies a tolerance or exemption for a pesticide chemical residue. Section 408(l)(5) applies to any tolerance action taken under Section 408 and not just those actions based on a finding in whole or in part of unacceptable dietary risk. EPA statistics on tolerance revocations indicate that over 1800 tolerance revocations have been issued between 1997 and 2002 that involve approximately 200 pesticides. NFPA has not analyzed these actions in detail. However, it is likely many were the result of voluntary actions taken by registrants, or EPA initiative to remove tolerances for which registrations were removed some time in the past, and/or a tolerance

was determined to be unnecessary due to the finding that no residue is likely, such as in animal products. Clearly, FDA did not act on all these tolerance actions in that FDA issued Level 1 guidance for the channels of trade provision for two of these pesticides. Preparation of a FDA Level 1 guidance may not have been justified in the vast majority of past tolerance revocations. However, NFPA believes these tolerance actions are covered under the channels of trade provision as envisioned in the passage of the Food Quality Protection Act. NFPA urges FDA to recognize that the effort faced both by the Agency and the food industry may be more extensive than indicated in the Agency's regulatory impact analysis and to elaborate on the Agency's interpretation of which tolerance actions are subject to the channels of trade provision and which are not.

Holding foreign entities to the pesticide cancellation date for purposes of determining the period of presumed legal application of a pesticide may negate the legal standing of US tolerances.

Under the Draft Guidance, FDA proposes to hold foreign uses of a pesticide to the same enforcement approach as for domestic foods. In taking this approach, additional burdens may be imposed on domestic responsible parties that base purchase decisions on import commodity/product compliance with an existing tolerance. NFPA stresses that there are practical limits to the opportunity and ability of US industry to directly monitor and/or directly control pesticide use in other countries in response to changes in FIFRA regulations that did not, and may not in the future, have any legal standing or relevance in other countries.

NFPA urges FDA to discuss the Agency's view of how a showing of legal application might be made with respect to commodities that are imported or derived from imported commodities in which the imported product was in compliance with an established EPA tolerance at the time of purchase and the presence of a legal residue extends beyond the period of presumed legal domestic application. The Draft Guidance suggests that a responsible party for a food found to contain a pesticide residue due to an imported commodity or ingredient after the period of presumed legal application would not be able to demonstrate legal application. NFPA believes that in the infrequent circumstances where this situation might arise, the responsible party would be able to demonstrate legal application of the pesticide by showing that the imported product was purchased when a legal US tolerance existed rather than having to document that the foreign use of the pesticide was in accordance with the registration cancellation date established under FIFRA. The clarification NFPA seeks is for those situations where a tolerance revocation is not due to an imminent health concern.

Conclusion

NFPA appreciates FDA's effort to improve the effectiveness and efficiency of applying the channels of trade provision. Because of the diversity of situations as determined by the potentially relevant pesticides, commodities, and food products, the continued

development of case-by-case guidance is appropriate. Care continues to be needed to make sure potentially affected "responsible parties" are involved in and informed of actions in a timely and effective manner.

NFPA thanks FDA for this opportunity to comment and will gladly respond to questions you may have.

Regards,

John R. Cady